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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sterzer et al.

Serial No.: 10/822,367

Filed: April 12, 2004

Title: INFLATABLE BALLOON CATHETER STRUCTURAL DESIGNS
AND METHODS FOR TREATING DISEASED TISSUE
OF A PATIENT

Art Unit: 3739

Examiner: Rosiland Stacie Rollins

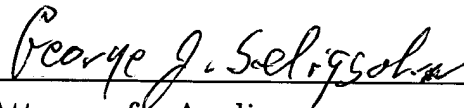
APPEAL BRIEF COVER LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-14501

Sir:

In response to the "NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF" of July 5, 2005, please substitute the enclosed Applicant's Appeal Brief (in triplicate), which does comply with the requirements of 37 CFR 1.192(c), for the original non-compliant Applicant's Appeal Brief filed in triplicate on June 6, 2005.

Respectfully submitted,



Attorney for Applicant

Registration No. 16933

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CERTIFICATE OF MAILING

I hereby certify that the attached correspondence is being deposited with the United States Postal Service by me on the date shown below with sufficient postage as first class mail in an envelope addressed to the:

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7-28-05
Date

George J. Seligsohn
Signature

George J. Seligsohn
Printed Name



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

Applicant: Sterzer et al.

Appeal No.

Serial No.: 10/822,367

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Title: INFLATABLE BALLOON CATHETER STRUCTURAL DESIGNS
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OF A PATIENT

Art Unit: 3739

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APPLICANT'S APPEAL BRIEF

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-14501

Sir:

Each of the following nine (9) items, being set forth in order, of this Appeal Brief (being filed in triplicate) is in accordance of the requirements of 37 CFR 1.192(c):

1. The real party in interest is MMTC, Inc., which is the assignee of an assignment recorded in the Patent and Trademark Office. Assignor and co-applicant Fred Sterzer is the president and principal stockholder of MMTC. Inc. Assignor and co-applicant Daniel D. Mawhinney is a stockholder of MMTC.
2. There are no related appeals and interferences.
3. There are 17 claims in this application, all of which are being appealed. Independent Claim 1, as amended by the amendment filed October 1, 2004, is being appealed. Each of original Claims 2-8, dependent on amended Claim 1, is being appealed. Independent Claim 9, as amended by

the amendment filed October 1, 2004, is being appealed. Each of original Claims 10, 11 and 17, dependent on amended Claim 9, is being appealed. Claim 12, dependent on amended Claim 9, as also amended by the amendment under 37 CFR 1.116 filed February 11, 2005, is being appealed. Each of original Claims 13-16, dependent on amended Claim 12, is being appealed.

4. It is believed that the amendment under 37 CFR 1.116 of dependent Claim 12 to overcome the final rejection thereof under 35 U.S.C. 112 (second paragraph) has been entered for the purposes of this Appeal.

5. SUMMARY OF THE INVENTION

Applicant's invention is directed to balloon catheter designs which incorporate an antenna cooperatively situated with respect to an external balloon surface for use in treating diseased tissue of a patient. The respective teachings of prior-art United States patent application 10/337,159 (now US patent 6,847,848 B2) and United States patents 5,007,437, 5,992,419 and 4,190,053 (page 1, line 21 to page 2, line 18) are incorporated by reference. FIGURE 1 (described page 3, line 25 to page 4, line 6) shows an example of a typical microwave prior-art balloon catheter design for treating diseased prostate tissue of a patient. This catheter design, in use, includes an internal antenna situated within an inflated balloon in which the antenna is separated from the exterior surface of the balloon pressing the urethral tissue proximate to the diseased prostate tissue by the balloon-inflating fluid (e.g. water). FIGURS 2a, 2b and 2c (described on page 4, line 7 to page 5, line 19) show an experimental embodiment of applicant's invention that employs a directional spiral antenna situated on the external surface of a longitudinally-split silicone-rubber tube that surrounds the catheter balloon. FIGURS 3a, 3b, 4a, 4b, 5a and 5b (described on page 5, line 20 to page 6, line 29) show a first preferred embodiment of the present invention which, like the experimental embodiment of FIGURS 2a, 2b and 2c, also employs a directional spiral antenna situated on the external surface of a longitudinally-split silicone-rubber tube that surrounds the catheter balloon. In addition, this first preferred embodiment employs an inlet lumen to transport a coolant fluid (either a gas or preferentially a liquid, such as water having a high heat capacity) to fill and thereby inflate the catheter balloon and an outlet lumen to extract coolant fluid from the catheter balloon. For cooling purposes, the coolant fluid may be continuously pumped through the catheter balloon. FIGURE 6 (described on page 6, line 30 to page 10, line 30) shows the use of this first preferred embodiment in the treatment of diseased prostate tissue, such as malignant tumor tissue within non-diseased prostate tissue or Benign Prostatic Hypertrophy (BPH). The directional spiral antenna, which is situated in cooperative relationship with the exterior surface of a coolant-fluid inflated catheter balloon, is in direct and intimate contact with the

urethral lining tissue overlying the non-diseased prostate tissue located closest to the diseased malignant tumor tissue. This arrangement causes the pattern of the microwave radiation transmitted from the external directional antenna and directed toward the malignant tumor tissue to be spatially confined to and effect only the desired heating of the targeted malignant tumor tissue and the undesired heating of the intervening healthy prostate tissue, as well as the lining tissue of urethra. The undesired heating of the intervening healthy prostate tissue and lining tissue of urethra is limited to a maximum safe temperature of 42°C by the continuously-flowing, high heat capacity coolant fluid (e.g. water), while a multi-frequency microwave radiometer continuously measures the temperature of the heated tissues. Further, this continuously-measured temperature by the multi-frequency microwave radiometer may be both fed back to the microwave power generator to control the power output thereof supplied to the radiating antenna and to control the amount of coolant fluid cooling. This makes it feasible to minimize the amount of microwave power needed, while maximizing the proportion of the radiation absorbed by the targeted tumor tissue and minimizing the proportion of the radiation absorbed by all of the intervening substance between the radiating antenna and the targeted tumor tissue. In the case of FIGURE 6, where external directional antenna is in direct contact with the lining tissue of urethra, the intervening substance is confined to only the lining tissue of urethra and the healthy prostate tissue. Further, by also measuring the surface temperature of the urethral lining tissue, a computer can use readings of the surface and radiometric temperatures to control both the amount of microwave heating and surface cooling in order to generate the desired optimum temperature distributions. In particular, the depth of heating is controlled by providing colder surface temperatures, which results in more power being delivered to the underlying diseased tissue (e.g., prostate malignant tumor tissue) without damaging the surface tissues. Thus, the deeper will be the depth of heating of the underlying diseased tissue. In particular, overheating of the sphincters of the urethra, with consequent damage thereto is avoided by such spatially-localized heating of targeted diseased prostate tissue (e.g. prostate

cancer lesions or BPH) to a temperature high enough to cause ablation thereof or to cause the urethral tissue lining the prostate to form a "biological stent" (disclosed in prior-art United States patent 5,992,419) in the urethra because the tissue surrounding the urethra can be safely raised to higher temperatures than is safely possible with conventional balloon catheters. FIGURES 7a and 7b (described on page 10, line 23 to page 11, line 25) shows a second preferred embodiment of the present invention that comprises (1) a helical omnidirectional monopole antenna situated in cooperative relationship with the exterior surface of the balloon of a balloon catheter and (2) coolant-fluid inlet and outlet lumens situated within the catheter. More specifically, the antenna constitutes metallic helical spring windings enveloping the exterior longitudinal surface of the balloon in a deflated state, with the most proximate winding of the spring being attached to the inner conductor of a microwave feedline thereto. When the balloon is inflated, the spring tends to unwind under balloon pressure, thereby increasing its diameter so that it remains in proximity to the exterior surface of the balloon in its inflated state. Thereafter, when the balloon is deflated, the restoring force of the spring returns it to its neutral state. A balloon catheter incorporating an antenna having this helical omnidirectional configuration would be particularly suitable for use as an interstitial probe, for treating subcutaneous diseased tissue of a patient, such as (1) deep-seated tumors and (2) varicose veins, as disclosed in the aforesaid prior-art United States patent application 10/337,159. In addition to the first and second preferred embodiments of the present invention described above, the external antenna's configuration (page 11, line 26 to page 12, line 8) may comprise metallic printing directly on the exterior surface of the balloon. (In the case of a spiral microstrip configuration, the metallic ground plane would be directly printed on the internal surface of the balloon.)

6. THE ISSUES

6(a). The Structural Issue:

The structural issue is whether or not, under 35 U.S.C. 102, the use in cited Kasevich et al. (US 5057106) of the phrase "outside the balloon", included in the sentence "In accordance with one embodiment of the invention, a printed microstrip circuit radiator or antenna pattern is configured in one of several ways, such as inside the balloon, between the balloon surfaces or outside the balloon." (Column 5, lines 33-37), anticipates the structure defined in applicant's amended independent Claims 1 and 9, despite the fact that the structure defined in applicant's amended Claims 1 and 9 cannot be read on any of the drawing Figures of Kasevich et al.

6(b). The Functional Issue:

The functional issue is whether or not the teaching of the Kasevich et al. invention, wherein to Microwave Balloon Angioplasty is used to heat plaque clogging a patient's blood vessels without heating the underlying blood vessel tissue, suggests the teaching of applicant's invention, wherein a patient's diseased tissue may be heated sufficiently by absorbed microwave radiation to form a "biologic stent" or to cause ablation or necrosis thereof, without overheating the proximate non-diseased tissue of the patient.

7. Independent amended Claims 1 and 9 and dependent Claims 2-8, 10 and 17, are rejected on Kasevich et al. (US 5057106) alone, and dependent Claim 11, amended dependent Claim 12 and dependent Claims 13-16 are rejected on Kasevich et al. in view of Sterzer et al. (US 5688050). Since Kasevich et al. is the sole or primary reference, and the novelty clause of each of independent amended Claims 1 and 9, written in Jepson form, has been amended in a similar manner, amended Claim 1 is selected from the entire group of 17 claims being appealed.

8. APPLICANT'S ARGUMENT

It is agreed that the novelty clause of original filed independent Claim 1, written in Jepson form, could be construed to read on any external antenna that is situated outside of the balloon surface. Therefore, the Examiner, in her first Office action of 7-23-04, was correct in her rejection of this claim based on the phrase "outside t-he balloon (Kasevich et al. Column 5, line 37), included in the sentence "In accordance with one embodiment of the invention, a printed microstrip circuit radiator or antenna pattern is configured in one of several ways, such as inside the balloon, between the balloon surfaces or outside the balloon (Kasevich et al. Column 5, lines 33-37).", since Fig. 14 of Kasevich et al. (discussed in detail below) shows an external antenna that is situated outside of the balloon surface. NOTE: Fig. 4 of Kasevich et al., relied on by the Examiner in her first Office action of 7-23-04, is directed to an antenna "embedded in balloon skin", not situated outside of the balloon.

Therefore, to overcome this rejection, the novelty clause of independent Claim 1, written in Jepson form was amended, in the amendment filed 10-1-04, to now state, "said antenna is longitudinally physically situated in cooperative relationship with said exterior surface of said balloon, thereby in use causing said inflated balloon pressing said diseased tissue to result in said antenna being in direct contact with irradiated tissue of said patient."

It is applicant's position that (1) the intended uses of the inflatable balloon catheter designs taught, respectively, by applicant and by Kasevich et al. are entirely different from one another and (2) because of this difference in intended use, Kasevich et al. intentionally avoids the teaching of an inflatable balloon catheter design for treating diseased tissue of a patient, which incorporates an antenna which is longitudinally physically situated in cooperative relationship with the exterior surface of the balloon, thereby in use causing the inflated balloon pressing the diseased tissue to result in the antenna being in direct contact with irradiated tissue of the patient, as called for in amended Claim 1.

The disclosed intended use of applicant's antenna situated in cooperative relationship with the exterior surface of the balloon is to heat the diseased tissue of a patient with absorbed radiant energy to a temperature high enough to cause necrosis of the diseased tissue, while still maintaining the neighboring non-diseased tissue of the patient at a safe temperature. This results from the fact that a such-situated antenna on an inflated balloon pressing the diseased tissue results in concentrating a very large proportion of a relatively large amount of transmitted radiant energy from the antenna in the diseased tissue, thereby limiting the amount of transmitted radiant energy from the antenna in the non-diseased tissue to a very small proportion. Examples of necrosis of the diseased tissue, while maintaining the neighboring non-diseased tissue at a safe temperature, disclosed by applicant are (1) destruction of malignant prostate tumor tissue (FIGURE 6 and Page 6, line 30 to Page 9, line 9), (2) producing "biological stents" (Page 9, lines 16-31), (3) ablating cancerous and BPH prostate tissue (Page 9, line 32 to Page 10, line 15), and (4) treating sub-cutaneous diseased tissue, such as deep-seated tumors and varicose veins (page 11, lines 21-25).

For all of the following reasons, it is Applicant's position that Kasevich et al. does not show, suggest or teach either the structure or function defined in this novelty clause of amended Claim 1, but, in fact, teaches away therefrom:

(a) Kasevich et al. states, "The present invention relates in general to microwave balloon angioplasty, and pertains more particularly to a microwave or radiofrequency catheter system for the heating of plaque in arteries or blood vessel (Column 1, lines 14-17)." The disclosed intended use of all but the Fig.14 one of the various antenna configurations of Kasevich et al., in the treatment of coronary vessel plaque with microwave balloon angioplasty is "to deliver microwave energy to a specific layer of plaque without heating wall tissue during pressure application by the balloon (Column 5, lines 15-17)." Further, Kasevich et al. states, "In accordance with the present invention, there are now described a number of techniques for providing control of the quantity of microwave energy that is coupled to coronary vessel plaque without

heating vessel tissue (Column 5, lines 27-31)." NOTE: the above-quoted sentence (2) is the first sentence in the Column 5, lines 27-37 paragraph which includes the phrase "outside the balloon" (relied on by the Examiner in rejecting amended Claim 1) on line 37 thereof. This Column 5, lines 27-37 paragraph occurs in Kasevich et al. prior to their description of any of the specific Figs. 1-36 of their drawing.

(b) FIGURES 1, 3, 6 and 13 of Kasevich et al. show different configurations of an antenna situated inside the balloon and FIGURES 4 and 5 of Kasevich et al. show different configurations of an antenna situated between the balloon surfaces, but only FIGURES 11 and 14 of Kasevich et al. comprise antenna structures that extend outside of the balloon. In the case of FIGURE 11 (described on Column 9, lines 22-49), the antenna structure comprises (1) a guide wire passing through the entire length of the balloon and terminating in tip 92 situated outside the distal end of the balloon and (2) chokes A and B situated within the balloon, respectively, in the vicinity of the proximate and distal ends of thereof. This results in only the portion of the guide wire between chokes A and B inside the balloon operating as a radiator. Therefore, tip 92 of FIGURE 11 cannot be considered a radiator situated outside of the balloon. However, FIGURE 14 (described on Column 6, lines 3-16), which comprises an antenna extending through the length of the balloon and terminating in a tip situated outside of the distal end of the balloon which has a ferrite layer thereon which is heated by microwave energy in the antenna, The heated ferrite at the antenna tip, with the balloon in a deflated state, may be used to melt, ablate and remove some plaque from a fully-blocked artery. Once some plaque has been removed, the balloon may be inflated and the microwave angioplasty carried out. Thus, the only one of the various antenna configurations of Kasevich et al. that includes an antenna configuration "outside the balloon" is shown in their FIGURE 14 (the structure of which may be modified as shown in FIGURE 27). Kasevich et al. state, "FIG. 14 shows the antenna A extending through the balloon B and having at its tip T a concentric layer of ferrite material that may

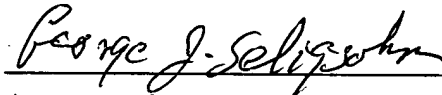
have a Curie temperature in the 400°C-500°C range. Microwave energy is rapidly absorbed in the ferrite when this material is at a current maximum of the antenna. The primary function of this hot tip (when the ferrite is at the far end of the antenna) is to melt plaque (ablation). This is used for those cases where the artery is fully blocked by plaque, and it would therefore be necessary to remove some plaque in order to insert the balloon. In FIG. 14, note the plaque volume at V. Once some plaque has been removed, the balloon may be inflated and the microwave angioplasty carried out (Column 6, lines 3-16). "Kasevich et al. further state, "As indicated previously, FIG. 27 herein teaches the use of a lossy sleeve 80 for focused heating. An alternate embodiment is to employ two ferrite sleeves F1 and F2, as illustrated in FIG. 14, some distance apart along the antenna axis but outside of and essentially in front of the balloon. In this regard, the arrow A1 in FIG. 14 illustrates the direction of the insertion of the antenna structure." (Column 6, lines 17-23).). Kasevich et al. still further state, "As indicated previously, FIG. 14 shows a two-ferrite geometry. The ferrites F1 and F2 heat through the plaque (occluded artery) using microwave frequency F1. To withdraw the antenna back through the plaque and avoid sticking, the ferrite F2 is tuned to a frequency F2. It remains hot to allow the antenna to be withdrawn prior to inserting the balloon and using the antenna in its normal plaque welding mode. Also, ferrite, hot tip antenna may be completely removed from the catheter in a different antenna design employed for low temperature operation." (Column 6, lines 24-34). It is plain from the above-quoted statements of Kasevich et al. that the "outside the balloon" antenna configuration, shown in FIGURE 14 of Kasevich et al., does not structurally or functionally show, or even suggest, an inflatable balloon catheter design for treating diseased tissue of a patient, which incorporates an antenna which is longitudinally physically situated in cooperative relationship with the exterior surface of the balloon, thereby in use causing the inflated balloon pressing the diseased tissue to result in the antenna being in direct contact with irradiated tissue of the patient, as called for in amended Claim 1.

(c) In her Final Rejection of 1-13-05, the Examiner maintained all her grounds of rejection of Claims 1-17. However, in the telephone interview of 1-31-05 with applicant's attorney, the Examiner did agree that amended Claim 1 could not be read on the structure shown in any of the drawing Figures of Kasevich et al. Nevertheless, it is still the Examiner's position that the single phrase "outside the balloon (Column 5, line 37)", all by itself, is sufficient structural disclosure to anticipate the structure defined in amended Claim 1. The fact is that, for all the reasons set forth above in (a) and (b), the microwave angioplasty catheter system of Kasevich et al. in use is purposely designed to not cause the inflated balloon pressing any tissue to result in their antenna being placed in direct contact with irradiated tissue of the patient (just the opposite to what is called for in amended Claim 1). Therefore, the Examiner's position is untenable.

(d) It is noted that both applicant's antenna configuration, which is situated in cooperative relationship with the exterior surface of the balloon, and the FIGURE 4 antenna configuration of Kasevich et al., in which the antenna is embedded in the skin of the balloon, share the microwave-efficiency advantage over those antenna configurations in which the antenna is situated inside of the balloon by not wasting radiated microwave energy in heating the coolant fluid inflating the balloon. However, the structural complexity of the FIGURE 4 skin-embedded antenna configuration of Kasevich et al. is significantly greater than that of applicant's simple configuration of merely situating the antenna in cooperative relationship with the exterior surface of the balloon. The question arises as to why Kasevich et al. chose this more complex antenna configuration. It is believed that the reason for their choice was to avoid unwanted heating of vessel wall tissue. (See Column 5, lines 15-17 and lines 27-31, discussed above in (a)). Therefore, the rational inference is that the failure of Kasevich et al. in their Microwave Balloon Angioplasty disclosure to show or teach the configuration of situating the antenna in cooperative relationship with the exterior surface of the balloon was not an oversight on their part, but was deliberate.

For all the reasons set forth above in Applicant's Argument, the Board of Patent Appeals and Interferences is respectfully urged to reverse the final rejection by the Examiner of (1) amended independent Claim 1, together with dependent Claims 1-8, amended independent Claim 9, dependent Claims 10 and dependent Claim 17 under 35 U.S.C. 102(b) as anticipated by Kasevich et al. (US 5057106) and (2) dependent Claim 11, amended dependent Claim 12 and dependent Claims 13-16 under 35 U.S.C. 103(a) as unpatentable over the primary reference Kasevich et al. further in view of Sterzer et al. (US 5688050), and allow each of these Claims 1-17.

Respectfully submitted,



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Appendix

9. APPEALED CLAIMS

1. In a balloon catheter suitable for use in treating diseased tissue of a patient, wherein said balloon catheter comprises a catheter body, an inflatable balloon surrounding said catheter body, and an antenna, wherein in use (1) said catheter with said balloon in a deflated state may first be positioned so that said antenna is aligned with said patient's diseased tissue and (2) said balloon may then be inflated so that an exterior surface of said balloon presses said diseased tissue while said antenna transmits radiant energy to said diseased tissue thereby to effect the heating of said diseased tissue; the improvement wherein:

said antenna is longitudinally physically situated in cooperative relationship with said exterior surface of said balloon, thereby in use causing said inflated balloon pressing said diseased tissue to result in said antenna being in direct contact with irradiated tissue of said patient.

2. The balloon catheter defined in Claim 1, wherein said catheter body comprises:

an input lumen that provides a first pathway for coolant fluid from a source situated outside of said balloon catheter to enter said balloon; and

an output lumen that provides a second pathway for said to leave said balloon and exit said balloon catheter.

3. The balloon catheter defined in Claim 1, wherein:
said external antenna is a directional antenna.
4. The balloon catheter defined in Claim 3, wherein:
said external directional antenna comprises a spiral microstrip structure.
5. The balloon catheter defined in Claim 4, wherein said spiral microstrip structure comprises:
longitudinally-split plastic tubing having an inner longitudinal surface thereof enveloping said longitudinal external surface of said balloon with a metallic ground plane portion of said external directional antenna directly attached to said inner longitudinal surface of said tubing and a metallic spiral portion of said external directional antenna directly attached to an outer longitudinal surface of said tubing.
6. The balloon catheter defined in Claim 1, wherein:
said external antenna is an omnidirectional antenna.
7. The balloon catheter defined in Claim 6, wherein:
said external omnidirectional antenna comprises a metallic helical structure surrounding said longitudinal external surface of said balloon.

8. The balloon catheter defined in Claim 1, wherein:

said external antenna is an external microwave antenna for transmitting microwave radiant energy to said diseased tissue while said balloon is inflated thereby to effect the heating of said diseased tissue.

9. In a system suitable for use in heat treating diseased prostate tissue of a patient, wherein said system comprises a balloon catheter including a catheter body, an inflatable balloon surrounding said catheter body, and an antenna; wherein in use (1) said catheter with said balloon in a deflated state may first be inserted into an orifice of said patient and positioned so that said antenna is aligned with said patient's prostate tissue and (2) said balloon may then be inflated so that an exterior surface of said balloon presses against lining tissue of said orifice that is adjacent to said patient's prostate tissue, the improvement wherein:

said antenna is a directional antenna that (1) is longitudinally physically situated in cooperative relationship with said exterior surface of said balloon, thereby in use causing said inflated balloon pressing against said lining tissue of said orifice that is adjacent to said patient's prostate tissue, to result in said antenna being in direct contact with said lining tissue of said patient and (2) transmits radiant energy of a given frequency band to said diseased prostate tissue in response to power within said given frequency band being supplied to said antenna; and

a power source and means including a feedline for supplying a given amount of power within said given frequency band to said external

directional antenna, thereby to irradiate said diseased tissue and thereby effect the heating to a given therapeutic temperature.

10 . The system defined in Claim 9, wherein:

said given frequency band is the 915 MHz frequency band.

11 . The system defined in Claim 9, wherein said system further comprises a radiometer, and wherein:

said means including a feedline further includes a single-pole two-position switch for forwarding said given amount of power within said given frequency band from said power source to said feedline when said single-pole two-position switch is in a first switch position thereof and for forwarding thermal radiation received by said external directional antenna and supplied to said feedline to said radiometer when said single-pole two-position switch is in a second switch position thereof;

whereby said radiometer provides a reading indicative of the temperature of said irradiated diseased tissue.

12 . The system defined in Claim 11, wherein:

said means including a feedline further includes means for switching said single-pole two-position switch back and forth between its first and second switch positions thereby to continuously provide from said radiometer a reading of said irradiated diseased tissue's current temperature.

13. The system defined in Claim 12, wherein said balloon catheter comprises:

means for supplying said balloon's interior volume with a coolant fluid for removing heat from said lining tissue of said orifice thereby to maintain the temperature of said lining tissue of said orifice at a safe temperature.

14. The system defined in Claim 13, wherein:

said safe temperature is no higher than 42°C.

15. The system defined in Claim 13, wherein said balloon catheter comprises a catheter body surrounded by said balloon thereof, and said means for supplying said balloon's interior volume with a coolant fluid comprises:

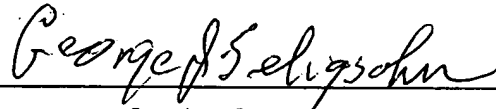
an input lumen in said catheter body that provides a first pathway for coolant fluid from a source situated outside of said balloon catheter to enter said balloon; and

an output lumen in said catheter body that provides a second pathway for said to leave said balloon and exit said balloon catheter.

16 . The system defined in Claim 15, wherein said orifice of said patient is said patient's urethra.

17 . The system defined in Claim 9, wherein said orifice of said patient is said patient's urethra.

Respectfully submitted,

A handwritten signature in cursive script, reading "George Seligson", is written over a horizontal line.

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